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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,713	02/24/2006	Marc Ramael	DECL112.001APC	5935

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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03/31/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/569,713	Applicant(s) RAMAEL ET AL.	
	Examiner GARY W. COUNTS	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: On page 50, line 32 the disclosure “enzym” should be –enzyme--.

Appropriate correction is required.

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Sequence Compliance

3. The specification lists sequences on page 41, lines 5-7, e.g., GGATTATTGTAAATATTGATAAGGA, there has been no CRF submitted or paper copy of the “Sequence listing”. Further, The sequences listed in the specification should include sequence identifiers.

Appropriate correction is required.

(1) The application clearly fails to comply with the requirement of 37 C.F.R. 1.821-1.825. Applicant’s attention is directed to the final rulemaking notice published at 55 FR 18230 (May, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

(2) This application does not contain, as a separate part of the disclosure on paper copy, a “Sequence Listing” as required by 37 C.F.R. 1.821(c).

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(3) A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

Applicant must provide:

An initial or substitute computer readable from (CFR) copy of the "Sequence Listing".

An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include not new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

The time for reply of the sequence compliance is set to the time of reply for the office action.

For questions regarding compliance to these requirements, please contact :

For Rules Interpretation, call (571) 272-2510

For CRF Submission Help, call (571) 272-2501/2583

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A washing step(s) critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). On page

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45, lines 19-21 discloses that labeled antibody is added and then wash steps performed. Page 62, lines 20-27 discloses that labeled antibody is added and then wash steps performed before detection. It appears that all embodiments contained within the specification include wash steps to remove unbound labeled antibody. The instantly recited claims recite labeled antibodies and labeled polypeptides utilized in the method but do not require a wash step. The invention as recited cannot work because if the unbound labeled antibody and unbound labeled polypeptide is not removed from the assay system there will be a continuous false positive reaction that would occur and one would not be able to differentiate bound from unbound labeled antibody or polypeptide. Therefore, a wash step(s) to remove unbound labeled polypeptide and unbound labeled antibody must be incorporated in order for the invention as claimed to be enabled.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7 and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 steps (a) –(b) are vague and indefinite because it is unclear what relationship exists between the components and one or more probes of step (a) and the one or more tagged probes and the tag-labeled sample comprising components of step (b). Does the components of (a) bind or somehow react with the tag-labeled sample comprising components? Does the components of (a) bind or react with the one or

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more tagged probes in (b)? Also, what is the relationship of the components of step (a) with the reagents of step (b)? What happens if one or more probes of step (a) are incubated with one or more tagged probes of step (b)? Method claims should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting and detecting. Method steps should clearly state each component used in the method and the relationship of the various components, and should not be a mere cataloging of parts. The claims should also conclude with a step relating the method result to the purpose of the method, preferably to the purpose as also set forth in the preamble of the claim.

Claim 1 step (b) is vague and indefinite because it is unclear if the sample is tagged or if the components of the sample are tagged. The preamble of the claim recites detecting one or more components. Thus, it appears that the components of step (b) would need to be tagged to provide for detection. The claim as currently recited does not make clear if the sample is tagged or if the components are tagged. Please clarify.

Claim 4, line 4 the recitation "step e1)" is vague and indefinite. It is unclear what applicant is referring to. There is no step e1 recited in the claims. Please clarify.

Claim 5 is vague and indefinite because it contradicts Claim 1. Claim 1 requires applying one or more samples comprising components to be detected or one or more probes onto a solid support. However, claim 5 recites that step a) is not performed by the user. Is step a performed or not? It is unclear what applicant intends to encompass.

Claim 5 the recitation "the user" there is insufficient antecedent basis for this limitation.

Claim 7, line 3 the recitation "the positions" there is insufficient antecedent basis for this limitation.

Conclusion

8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hechinger (US 2003/0008410) disclose methods for detecting one or more analytes in a sample. Hechinger disclose the use of multiple antibodies for the detection process and teaches an attached indicator system.

LaMotte, III (US 5,296,347) disclose immunoassay methods comprising multiple antibodies with labels and tags for detecting an analyte of interest.

Nilsen (US 6,110,687) disclose antibody conjugates used in methods for detecting analytes.

Lansdorp (US 4,868,109) disclose an antibody complex comprising two different antibodies. Lansdorp disclose that this complex is used as a labeled antibody in immunoassays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641